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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,789	05/15/2001	Pablo Rubinstein	63475/267	9553

7590

07/15/2003

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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

13

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

2 C

Office Action Summary	Application No. 09/855,789	Applicant(s) RUBINSTEIN ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,27,28,30 and 31 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/4/03 has been entered.

As requested, the previously filed amendment, filed 4/2/03, has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25 & 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's claims are directed to a therapeutic product obtained from cord or placental blood "wherein the therapeutic product comprises white blood cells, less than all of plasma and red blood cells contained in said cord blood or placental blood." The claim language ***less than all of plasma and red blood cells*** is still indefinite. As best can be understood by the examiner, *less than* indicates the plasma and red blood cells have been removed from the cord or placental blood to form said therapeutic product. For purposes of

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examination, the therapeutic product has been interpreted as white blood cells from cord or placental blood and a cyroprotective agent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Rubinstein et al. ("Stored Placental Blood for Unrelated Bone Marrow Reconstitution," May 1993). As stated above, as best understood by the examiner, the "therapeutic product" may be cord or placental blood and a cyroprotective agent. Rubinstein et al. disclose that placental blood may be recovered and frozen for future procedures. Rubinstein et al also disclose that DMSO, a cyroprotective agent, is added to the placental blood, at an optimal cooling rate, prior to freezing to ensure leukocyte viability. Since Rubinstein et al. disclose that the placental blood is not subjected to fractionation prior to freezing and that the cooling rate is optimized to ensure viability, it is inherent that at least 80% of the white blood cells (leukocytes) is attained. (See "Practical issues" on pages 13-14 of article)

Claims 25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyse et al. (5,004,681). As stated above, as best understood by the examiner, the "therapeutic product" may be white blood cells separated from cord or placental blood and a cyroprotective agent for future therapeutic use. Boyse et al. discloses cryopreservation of hematopoietic stem and progenitor cells (i.e. white blood cells) of blood. The cells may be obtained from cord blood and/or placental blood (col. 12, lines 54-60). The cells will have a cyroprotective agent added to them, such as DMSO or dextran. With respect to the use of DMSO, Boyse et al. states that a low concentration of DMSO is used (col. 12, lines 25-68).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyse et al. ('681). Boyse et al. discloses the invention substantially as claimed, see rejection supra. Boyse et al., however, fails to disclose specifically the specific concentration of DMSO used (10% DMSO in claim 30 and 1% DMSO in claim 31) and the osmolarity of the product is not more than 300 milliosmols. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a concentration of DMSO to be either 1% or 10%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, since Boyse et al. discloses that a low concentration of DMSO is used such general conditions are met. With respect to the osmolarity of the product is not more than 300 milliosmols, it would have been obvious to one having ordinary skill in the art at the time the invention was made to achieve this osmolarity, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

Claim 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Response to Arguments

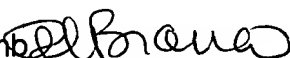
Applicant's arguments filed 4/2/03 have been fully considered but they are not persuasive. Applicant argues that neither Rubinstein et al. nor Boyse et al. teach of a therapeutic product that has a white cell viability greater than 80% after freezing and thawing of the therapeutic product. However, the claim language in applicant's claims of "after freezing and thawing of the therapeutic product" is a recitation of the intended use of the claimed product. It has been held that a recitation with respect to the manner in which a claimed apparatus or product is intended to be used does not differentiate the claim(s) from the prior art.

Conclusion

Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb 
July 12th, 2003